EXHIBIT G

Outcome After Anterior Vaginal Prolapse Repair

A Randomized Controlled Trial

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OBJECTIVES: To report 1-year outcomes of a randomized controlled trial comparing polypropylene mesh–reinforced anterior vaginal prolapse repair with anterior colporrhaphy.

METHODS: Seventy-six patients with stage II or greater anterior vaginal prolapse were randomly assigned to either colporrhaphy or polypropylene mesh repair. The primary outcome was recurrent stage II anterior vaginal prolapse, and secondary outcomes were effects on quality of life and sexual symptom scores, operative time, blood loss, length of hospitalization, and adverse events.

RESULTS: Thirty-eight women had anterior colporrhaphy, and 37 had polypropylene mesh repair. One patient allocated to mesh repair withdrew from the study before surgery. Clinical and demographic data did not differ significantly between the two treatment groups. One year after surgery, optimal and satisfactory anterior vaginal support were obtained in 21 of 38 (55%) of the colporrhaphy group and 33 of 38 (87%) of the mesh group (P=.005). Patients in both groups reported less bother after surgery in both prolapse and urinary symptoms. The rates of de novo dyspareunia were 4 of 26 (16%) and 2 of 23 (9%) in the colporrhaphy and mesh groups, respectively. Two of 37 (5%) patients had vaginal mesh extrusion. Nine anterior colporrhaphy patients would have to have recurrent anterior vaginal prolapse to prevent one vaginal mesh extrusion. Neither serious adverse events nor deaths occurred in either group.

CONCLUSION: Anterior vaginal prolapse repair with polypropylene mesh reinforcement offers lower anatomic recurrence than anterior colporrhaphy at one year. However, quality of life and sexual symptoms scores improved in both groups.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, www. clinicaltrials.gov, NCT00535301

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LEVEL OF EVIDENCE: I

Successful correction of anterior vaginal prolapse remains one of the most challenging aspects of pelvic reconstructive surgery. Up to 70% have recurrent prolapse after anterior colporrhaphy.[1,2] The low success rate has consequently led to widespread use of grafts in anterior vaginal prolapse repair. Although biologic grafts and polyglactin 910 mesh have yielded disappointing results,[1–5] uncontrolled studies have demonstrated low recurrence rates with polypropylene mesh reinforcement.[6–8]

The Perigee Transobturator Prolapse Repair System (polypropylene mesh repair, American Medical Systems, Minnetonka, MN) is used to repair anterior vaginal prolapse by a transobturator approach.[9,10] Specially designed helical needles are used to anchor either a porcine dermal (InteXen, American Medical Systems) or soft polypropylene (IntePro,American Medical Systems) graft to the pelvic sidewall at four points. We designed this randomized control trial to compare the anatomic success rates, effect on quality of life and sexual symptom scores, and rates of adverse events of the procedure with polypropylene mesh with that of anterior colporrhaphy, with planned follow-up of 3 years. This is a report of the 1-year interim analysis of the study.

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MATERIALS AND METHODS

This study was undertaken after obtaining approval from the Kaiser Permanente Institutional Review Board. Participants were recruited from the Female Pelvic Medicine and Reconstructive Surgery Clinic at Kaiser Permanente Bellflower Medical Center between January 2005 and April 2006. Women 21 years and older with stage II or greater anterior vaginal prolapse requiring surgical correction were eligible for participation. Patients were excluded if they had stage 0 or I anterior vaginal support, declined participation, were pregnant or contemplating future pregnancy, had prior anterior vaginal prolapse repair with biologic or synthetic graft, active or latent systemic infection, compromised immune system, uncontrolled diabetes mellitus, previous pelvic irradiation or cancer, known hypersensitivity to polypropylene, were unable or unwilling to give valid informed consent or comply with the requirements of the protocol, or if scheduled to undergo concomitant Burch colposuspension or pubovaginal sling. Undergoing other prolapse repairs did not preclude study participation and did not affect group assignment.

Baseline evaluation included a standardized history, validated quality of life (Pelvic Floor Distress Inventory [PFDI-20] and Pelvic Floor Impact Questionnaire [PFIQ-7])[11] and sexual function (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire [PISQ-12])[12] questionnaires, urinalysis, gynecologic and pelvic organ prolapse quantification (POP-Q)[13] examinations, and multichannel urodynamics with prolapse reduction. Menopausal patients were instructed to use estrogen vaginal cream at least 6 weeks before surgery and resume treatment 2 weeks after surgery.

Patients were randomly assigned by a computer-generated schedule to either anterior colporrhaphy or the polypropylene mesh repair with group assignment concealed in a sealed opaque envelope. The primary surgeon (J.N.N.) remained blinded to the group assignment until the day of surgery. Although the patients, research nurse, and medical assistant were also blinded to their group assignment, unblinding was permitted in case of a serious adverse event or upon patient insistence.

All surgical patients received perioperative intravenous antibiotic prophylaxis and vaginal infiltration with 0.25% bupivacaine and 1:200,000 epinephrine solution. Anterior colporrhaphy was performed through a midline anterior vaginal incision, dissection of the vaginal epithelium from the fibromuscular layer, midline plication of the fibromuscular layer with 2-0 polydioxanone suture, excision of excess vaginal mucosa, and incision closure with 2-0 polyglactin suture.

The polypropylene mesh repair procedure was also performed through an anterior midline vaginal incision (Fig. 1). Dissection of the vaginal mucosa from the fibromuscular layer was performed toward the inferior pubic rami and ischial spines without disruption of the arcus tendineus fascia pelvis. Midline fascial defects were repaired with 2–0 polydioxanone sutures before graft placement. The polypropylene mesh repair system's helical needles were placed transcutaneously through the medial portion of the obturator fossa and used to anchor the preformed polypropylene mesh along the arcus tendineus fascia pelvis at the level of the bladder neck and 1–2 cm caudal to the ischial spines. The proximal and distal ends of the mesh were trimmed to fit the dissected space without redundancy and secured to the endopelvic fascia and vaginal apex, respectively, with 2–0 polydioxanone suture. The body of the mesh was loosely tensioned so that a Mayo scissors could be easily placed between the mesh and bladder, and the mesh arms were not taught when palpated through the vaginal mucosa. The incision was closed using 2–0 polyglactin sutures without excision of vaginal mucosa. Other operative procedures were performed as indicated. The midline anterior vaginal incision was not connected to the apical incision if a hysterectomy was performed concomitantly. The vagina was packed overnight.

Postoperative evaluations were performed at 8 weeks, 6 months, 1 year, and annually thereafter. Prolapse staging and PFDI-20, PFIQ-7, and PISQ-12 questionnaires were performed at the 6-month and annual visits. The primary investigator performed the preoperative, 8-week, and 6-month postoperative examinations in all patients. A research nurse trained in POP-Q measurement and blinded to the patient's group assignment performed the 1-year and subsequent annual POP-Q staging and pelvic examinations. A medical assistant blinded to the patient's group assignment administered preoperative and postoperative PFDI-20, PFIQ-7, and PISQ-12 questionnaires.

The primary outcome measure was recurrent stage II anterior vaginal prolapse. Definitions conformed to recommendations from the National Institutes of Health Terminology Workshop for Researchers in Female Pelvic Floor Disorders.[14] Vaginal support was considered "optimal" when both points Aa and Ba were at stage 0 (–3 cm), and "satisfactory" when both points Aa and Ba were at stage I (–2 cm) and improved from preoperative staging. Anatomic

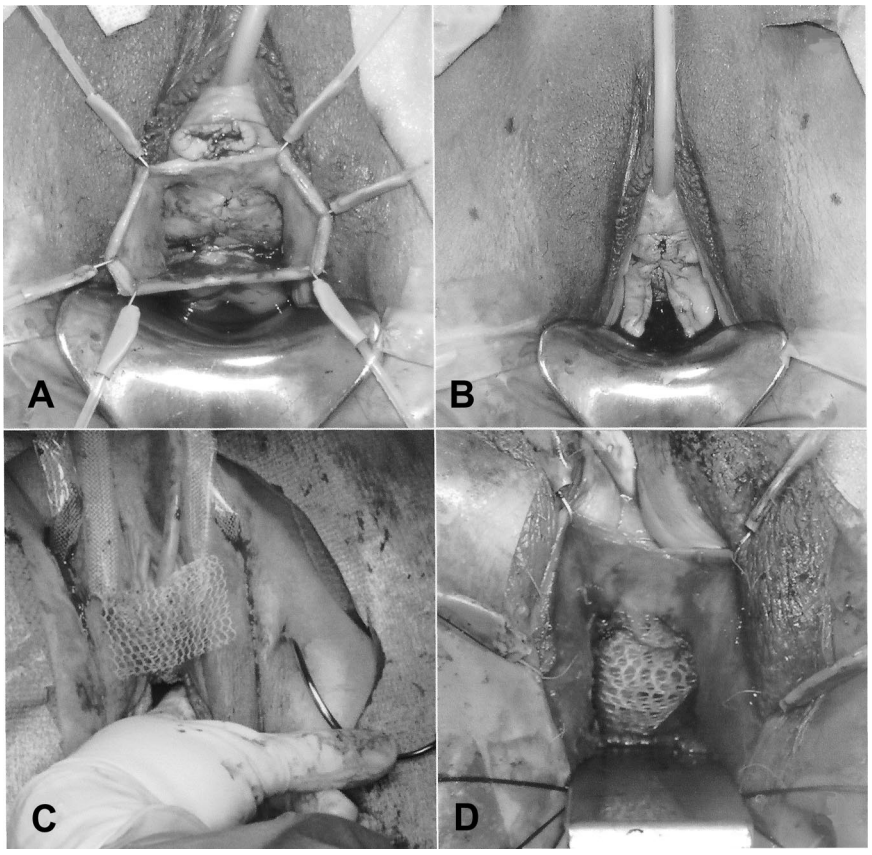

Fig. 1. Polypropylene mesh transobturator vaginal prolapse repair. **A.** Vaginal dissection and central fascial defect repair completed. **B.** Superior and inferior entry points for helical needles marked on the medial border of the obturator fossa. **C.** Passage of left inferior needle after completion of superior needle passages. **D.** Mesh tensioned loosely below the bladder.

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cure was defined as an optimal or satisfactory outcome. Anterior vaginal support was considered "unsatisfactory" (failure) if either point Aa or Ba was at stage II or beyond (–1 cm or lower). Secondary outcomes were operative time (from first incision to closure of last incision), blood loss (preoperative minus postoperative day one hemoglobin), length of hospitalization, adverse events, and PFDI-20, PFIQ-7, and PISQ-12 scores. Dyspareunia was considered significant if patients responded "usually" or "always" to item 5 of the PISQ-12 questionnaire.

Sample size was calculated based on previously published anatomic success rates of standard anterior colporrhaphy (50%) and polypropylene mesh–reinforced anterior vaginal repair (85%).[1–10] Assuming a two-tailed hypothesis test with 5% type I error and 80% power, 33 patients in each group would be required to detect an absolute difference of 35% or more in recurrent stage II prolapse. Assuming a 15% drop-out rate, we sought to enroll 76 patients into the clinical trial. An interim analysis was planned once all patients completed the 1-year follow-up.

Statistical analysis was performed using SAS statistical software (SAS Institute, Cary, NC). Continuous variables were compared with the two-tailed *t* test or Wilcoxon rank sum tests. Categorical variables were compared with the χ^2 or Fisher exact test. Recurrent prolapse was analyzed on an intention-to-treat basis. Preoperative and postoperative comparisons were made with the analysis of variance (ANOVA) or Wilcoxon signed rank test where appropriate. Statistical significance was set at $P<.05$. All terminology conformed to the guidelines proposed by the International Continence Society unless specified otherwise.[15]

RESULTS

Seventy six women were assigned to either anterior colporrhaphy or the polypropylene mesh repair system (Fig. 2). One patient allocated to the polypropylene mesh repair arm withdrew before implant and underwent anterior prolapse repair with porcine dermis. One patient who underwent anterior colporrhaphy did not return for her 1-year follow-up examination. Clinical and demographic data did not differ significantly between the two treatment groups (Table 1). The type and number of concomitant procedures performed, operative time, and length of hospitalization were similar in the two treatment groups. Although the median postoperative day one hemoglo-

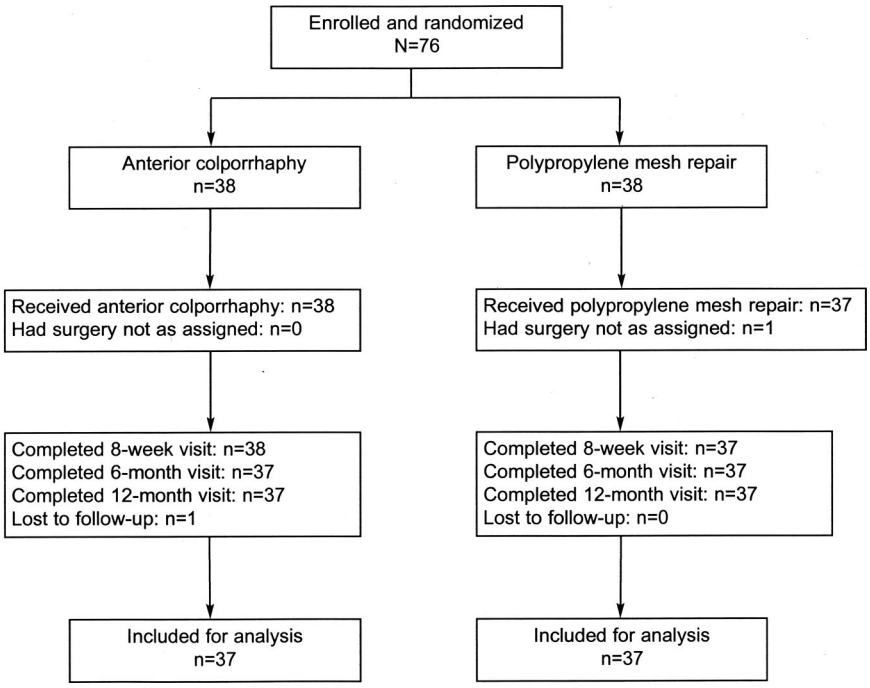

Fig. 2. Patient enrollment and follow-up.

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bin change was larger in the polypropylene mesh repair than in the anterior colporrhaphy group (2.4 g/dL compared with 1.8 g/dL, *P*=.02), the transfusion rates were similar. Urinary tract infection (11 in 75, 15%) was the most common postoperative adverse event in both groups. Postoperative unilateral leg pain occurred in 1 in 37 (3%) polypropylene mesh repair patient. This resolved with oral analgesics and was not present at her 8-week postoperative visit. Urinary retention occurred in four (5%) patients who had concomitant midurethral sling procedures. All four voided spontaneously after sling mobilization. There were no serious adverse events or deaths.

Two of 37 (5%) polypropylene mesh repair patients had asymptomatic 2- to 3-mm mesh extrusions along the anterior vaginal incision at their 6-month examination. Both were postmenopausal and not using either vaginal or oral estrogen. In both patients, there was no granulation tissue or evidence of infection, and the extrusions were successfully treated with in-office local excision and vaginal estrogen cream. There were no vaginal healing defects in either patient at one year.

One year after surgery, optimal and satisfactory anterior vaginal support were obtained in 21 of 38 (55%) of the colporrhaphy group and 33 of 37 (89%) of the polypropylene mesh repair group (*P*=.002) (odds ratio 6.7, 95% confidence interval 2–22). The difference in cure rates remained significant if the lost-to-follow-up patient in the anterior colporrhaphy group and the unimplanted polypropylene mesh repair patient were considered failures (21 of 38 [55%] compared with 33 of 38 [87%], *P*=.005) (odds ratio 5.3, 95% confidence interval 1.7–17). In both groups, points Ba, C, and Bp improved significantly after surgery (Table 2).

The PFDI-20 and PFIQ-7 scores were similar in the two treatment groups at baseline and improved significantly in both groups 6 and 12 months after surgery (Table 3). Symptom scores at 12 months did not differ significantly from those at 6 months. Patients in both groups reported less bother in the prolapse and urinary, but not the colorectal, subscales of the PFDI-20 and PFIQ-7. At 1 year, the Pelvic Organ Prolapse Distress Inventory-6 and Urinary Distress Inventory-6 scores were significantly lower, and the Colorectal-anal Distress Inventory-8 score was significantly higher in the polypropylene mesh repair group than the anterior colporrhaphy group. The prolapse, colorectal, and urinary subscales of the PFIQ-7 at 1 year did not differ significantly between the two treatment groups.

Preoperatively, 28 of 38 (74%) anterior colporrhaphy and 27 of 37 (73%) polypropylene mesh repair patients were sexually active. One year after surgery, 26 of 37 (70%) anterior colporrhaphy and 23 of 37 (58%) polypropylene mesh repair patients were sexually active. In the colporrhaphy group, one reported persistent dyspareunia and two did not give reasons for discontinuing sexual activity. In the polypro-

Table 1. Baseline Demographic and Clinical Data of the Two Surgical Groups

	AC (n=38)	Perigee (n=37)	*P*
Mean age±SD (y)	59 ± 9.5	61 ± 10.5	.73
Median (range) vaginal parity	3 (0–6)	3 (0–5)	.72
Mean BMI±SD (kg/m^2)	27±4	28±3	.59
Previous hysterectomy	12 (31)	16 (43)	.42
Previous prolapse surgery	6 (16)	8 (22)	.56
Previous incontinence surgery	3 (8)	3 (8)	.99
Menopausal status			.64
Premenopausal	7 (18)	7 (19)	
Postmenopausal with HT	7 (18)	10 (27)	
Postmenopausal without HT	24 (64)	20 (54)	
Urodynamic stress incontinence	24 (64)	20 (54)	.57
Overactive bladder	12 (32)	10 (27)	.86
Anterior vaginal POP-Q stage			.44
Stage II	23 (61)	18 (49)	
Stage III	14 (37)	16 (43)	
Stage IV	1 (2)	3 (8)	
Concomitant surgical procedures			
Vaginal hysterectomy	20 (53)	17 (46)	.71
Salpingo-oophorectomy	11 (29)	9 (24)	.86
Uterosacral vaginal suspension	30 (79)	26 (70)	.33
Midurethral sling*	28 (74)	25 (68)	.54
Site-specific rectocele repair	9 (24)	8 (22)	.75
Perineoplasty	6 (16)	8 (22)	.67
Apogee prolapse repair	1 (3)	3 (8)	.35
Median (range) operative time (min)†	120 (60–150)	135 (65–210)	.50
Median (range) hemoglobin change (g/dL)‡	1.8 (1.0–2.5)	2.4 (0.5–3.7)	.02
Median (range) hospitalization length (d)	2 (1–3)	2 (1–3)	.33
Postoperative adverse events			
Fever	3 (8)	2 (5)	1.00
Blood transfusion	1 (3)	1 (3)	1.00
Urinary retention requiring intervention§	2 (5)	2 (5)	1.00
Urinary tract infection	7 (18)	4 (11)	.51
Transient leg pain	0	1 (3)	.49
Vaginal mesh exposure‖	0	2 (5)	.24

AC, anterior colporrhaphy; Perigee, polypropylene mesh repair; SD, standard deviation; HT, hormone therapy; POP-Q, pelvic organ prolapse quantification.
Data are n (%) unless otherwise specified.
* Transvaginal or transobturator tape.
† For all operative procedures combined.
‡ Preoperative hemoglobin minus hemoglobin obtained on the morning ofthe first postoperative day.
§ Patients returned to the operating room for sling mobilization. All voided successfully after the procedure.
‖ Two- to 3-mm exposure occurring at the previous anterior vaginal incision site.

pylene mesh repair group, three reported partner-related reasons and two did not give reasons for discontinuing sexual activity. One patient in each group resumed sexual activity after prolapse repair. Mean (±standard deviation) baseline PISQ-12 scores were similar in the two groups (*P*=.75) and did not change significantly in either the anterior colporrhaphy (32±4 compared with 33±3, *P*=.13) or polypropylene mesh repair (33±3 compared with 34±6, *P*=.07) group 1 year after surgery. The fraction of patients who reported "always or usually" having dyspareunia did not change significantly 1 year after surgery in either the anterior colporrhaphy group (six of 28 [21%] compared with three of 23 [13%], *P*=.92) or polypropylene mesh repair group (six of 27 [22%] compared with three of 23 [13%], *P*=.55). De novo dyspareunia at 1 year was reported in 4 of 26 (16%) and 2 of 23 (9%) of the anterior colporrhaphy and polypropylene mesh repair groups, respectively (*P*=.67). These rates did not differ significantly (6 of 26 [23%] compared with 4 of 23 [17%], *P*=.73) when the four patients who gave no reason for postoperative sexual inactivity were considered to be inactive due to dyspareunia.

One woman (3%) in the anterior colporrhaphy group had recurrent POP-Q stage II anterior vaginal prolapse (Ba 0, C –7, Bp –3) and stress urinary incontinence at 6 months. Her initial surgery con-

Table 2. POP-Q Measurements at Baseline and 1 Year After Surgery

	Baseline		1 Year		
	AC (n=38)	Perigee (n=37)	AC (n=37)	Perigee (n=37)	*P* Within Group (AC/Perigee)
Point Ba	2 (0–5)	2 (0–8)	−1 (−3, 1)	−2 (−3, 0)	.001/.001
Point C	−3.5 (−6 to 7)	−3 (−7 to 8)	−8 (−5 to −10)	−8 (−7 to −10)	.001/.001
Point Bp	−1.5 (−3 to 9)	−2 (−3 to 8)	−2 (−3 to 0)	−3 (−3 to 0)	.01/.001
TVL (cm)	10 (8–11)	10 (8–11)	9 (8–11)	9 (8–12)	.03/.04
GH (cm)	6 (4–8)	6 (4–8)	5 (3–6)	5 (4–6)	.53/.72

Data are median (range) unless otherwise specified.
AC, anterior colporrhaphy; Perigee, polypropylene mesh repair; TVL, total vaginal length, GH, genital hiatus.

sisted of vaginal hysterectomy, high uterosacral vaginal suspension, midurethral sling, and anterior colporrhaphy. The vaginal prolapse and incontinence became more bothersome and she subsequently underwent a Burch urethropexy and paravaginal repair 15 months after her initial surgery.

DISCUSSION

In this randomized controlled trial, the 1-year anatomic recurrence rate after polypropylene mesh–reinforced anterior vaginal prolapse repair was significantly lower than anterior colporrhaphy. Most of the recurrences were POP-Q stage II and not bothersome enough to warrant reoperation. Our anatomic recurrence rates for both procedures are consistent with that of other studies. Weber and colleagues[1] reported satisfactory or optimal anatomic results in 30% of patients after anterior colporrhaphy at a median follow-up 23.3 months. A recent randomized controlled trial demonstrated recurrent stage II or III anterior vaginal prolapse occurred less often when anterior colporrhaphy was performed with mesh reinforcement (6.7% compared with 38.5%, $P<.001$).[16]

Although anatomic support was better with the polypropylene mesh repair procedure, prolapse and incontinence symptoms improved significantly in both treatment groups. However, improvement in the prolapse and urinary subscales of the PFDI-20 were greater in the polypropylene mesh repair than the anterior colporrhaphy group. Additionally, patients with recurrent prolapse were not significantly bothered 1 year after surgery. Our stringent definition of anatomic failure may explain the high number of asymptomatic patients with recurrent prolapse and low re-operation rate 1 year after surgery.

Sexual symptom scores did not change significantly in either treatment group. Although the PISQ-12 score improved in the polypropylene mesh repair group, this change did not reach statistical significance. Kumesu and colleagues[17] reported im-

Table 3. Effect of Anterior Colporrhaphy and Perigee on Health-Related Quality of Life Scores

	Baseline		6 Months		1 Year			
	AC (n=38)	Perigee (n=37)	AC (n=37)	Perigee (n=37)	AC (n=37)	Perigee (n=37)	*P** Within Group (AC/Perigee)	*P* † Between Group (Baseline/1 y)
PFDI-20	109±58	108±45	38±25	34±32	45±32	34±31	<.001/<.001	.89/.13
POPDI-6	45±25	44±20	8±10	6±9	13±15	6±8	<.001/<.001	.88/.01
CRADI-8	11±16	16±15	8±10	13±13	7±12	13±15	.17/.50	.20/.04
UDI-6	53±29	48±27	22±18	15±16	25±18	15±15	<.001/<.001	.45/.01
PFIQ-7	82±54	77±54	19±26	19±28	23±31	14±23	<.001/<.001	.86/.20
POPIQ-7	31±23	34±22	1±6	2±6	3±7	1±4	<.001/<.001	.57/.17
CRAIQ-7	7±17	7±15	2±7	6±14	3±8	4±9	.10/.66	.90/.46
UIQ-7	44±30	38±32	16±24	11±16	17±26	9±16	<.001/<.001	.46/.11

AC, anterior colporrhaphy; Perigee, polypropylene mesh repair; PFDI-20, Pelvic Floor Distress Inventory; POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; CRADI-8, Colorectal-anal Distress Inventory-8; UDI-6, Urinary Distress Inventory-6; PFIQ-7, Pelvic Floor Impact Questionnaire-7; POPIQ-7, Pelvic Organ Prolapse Impact Questionnaire-7; CRAIQ-7, Colorectal-anal Impact Questionnaire-7; UIQ-7, Urinary Impact Questionnaire-7.
Data are mean±standard deviation unless otherwise specified.
The PFDI-20 and PFIQ-7 each have a range of 0 to 300, with higher scores indicating greater distress. Each of their respective subscales, POPDI-6, CRADI-8, UDI-6, POPDI-7, CRAIQ-7, and UIQ-7, have a range of 0 to 100 with higher scores indicating greater distress.
* Repeated measures analysis of variance.
† Student *t* test.

proved PISQ scores after prolapse and incontinence surgery. Rogers and colleagues[18] reported worsening of sexual function scores after surgery for prolapse and urinary incontinence despite improvement of incontinence 6 months after surgery. Our low dyspareunia rate was due to loose mesh tensioning and avoiding procedures, such as perineoplasty and levatorplasty, that constrict or shorten the vagina. Most patients reported postoperative dyspareunia secondary to vaginal dryness.

The long-term disposition of permanent mesh is of great concern. No erosions of mesh into the viscera occurred in this study. Admittedly, longer follow-up with a larger number of patients may be required to see these complications. Vaginal mesh extrusion did occur in two polypropylene mesh repair patients. These extrusions likely resulted from healing defects of the anterior vaginal incision. They resolved after local excision and treatment with vaginal estrogen cream. Given the 5% vaginal mesh extrusion rate, the number needed to harm would be 20. Given the 45% failure rate after anterior colporrhaphy, nine anterior colporrhaphy patients would have recurrent anterior vaginal prolapse to prevent one polypropylene mesh repair vaginal mesh extrusion.

The principal strength of this study was that it is a randomized controlled trial that used validated outcome measures assessed by blinded clinical examiners. Moreover, the surgical procedures were performed by one surgeon rather than multiple surgeons. Lastly, the lost to follow-up rate was significantly low at 1 in 75 (1.3%).

However, this study was subject to several limitations. The small number of patients in each treatment group and short follow-up may have limited our ability to detect uncommon adverse events and small differences in quality of life and sexual symptom scores. A cost–benefit analysis of using mesh kits to reduce anatomic recurrences was not performed in this study. Additionally, the majority of patients underwent concurrent pelvic reconstructive and antiincontinence procedures. As a result, improvements in anatomic and functional outcomes were likely due to a comprehensive surgical repair rather than isolated anterior vaginal prolapse repair. Although we cannot draw any definite conclusions regarding the effects of anterior colporrhaphy and polypropylene mesh–reinforced prolapse repair alone, we can conclude that polypropylene mesh–reinforced anterior prolapse repair is associated with a lower recurrence rate when used as part of a comprehensive surgical repair. We believe that our results are applicable to the general population because most patients undergo multiple pelvic reconstructive and incontinence procedures concurrently. Last, although this single-surgeon study increases homogeneity in surgical technique and results, it may not be as easily generalized to a diverse population of surgeons.

Despite these limitations, this study is one of few prospective studies comparing sutured with mesh-reinforced anterior vaginal prolapse repairs. Our results demonstrated that although visceral and sexual functions were improved after both anterior colporrhaphy and polypropylene mesh–reinforced repair, the latter was associated with a significantly lower short-term anatomic recurrence rate in both primary and secondary repairs. Because the long-term durability and safety of mesh-reinforced repair is unknown, surgeons may consider using these procedures for recurrent prolapse or primary repairs in cases where there is a high risk of recurrence and after discussion of risks, benefits, and alternatives.

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